

TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371

0471-0268P

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

10/009689

INTERNATIONAL APPLICATION NO.

PCT/EP00/05383

INTERNATIONAL FILING DATE

June 13, 2000

PRIORITY DATE CLAIMED

June 14, 1999

## TITLE OF INVENTION

PHARMACEUTICAL COMPOSITIONS CONTAINING 8-CHLORO-3 ( $\beta$ -DIETHYLAMINOETHYL)-4-METHYL-7-ETHOXYCARBONYL-METHOXY COUMARIN BASE AND THE SALTS THEREOF, WITH CHOLESTEROL-LOWERING\*

## APPLICANT(S) FOR DO/EO/US

BEVILACQUA, Carla; DI SANTE, Giuseppe; FINESSO, Mario

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39 (1).
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
- a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau). PCT/EP00/05383
- b. ☒ has been transmitted by the International Bureau.
- c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
- a. ☐ is transmitted herewith.
- b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4)
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
- a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
- b. ☐ have been transmitted by the International Bureau.
- c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
- d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 20. below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98, Form PTO-1449(s), and International Search Report (PCT/ISA/210 and PCT/ISA/220) with 3 cited document(s).
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A **FIRST** preliminary amendment.
14. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information:
1. PCT/IPEA/416
2. PCT/IPEA/409
3. Three (3) Sheets of Formal Drawings

\*ACTIVITY

U.S. APPLICATION NO (if known, see 37 CFR 1.5) <b>10/009689</b>		INTERNATIONAL APPLICATION NO PCT/EP00/05383		ATTORNEY'S DOCKET NUMBER 0471-0268P	
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<p>21. <input checked="" type="checkbox"/> The following fees are submitted:</p> <p><b>BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(5):</b>          Neither international preliminary examination fee (37 CFR 1.482)          nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO          and International Search Report not prepared by the EPO or JPO. .... <b>\$1,040.00</b></p> <p>International preliminary examination fee (37 CFR 1.482) not paid to          USPTO but International Search Report prepared by the EPO or JPO ..... <b>\$890.00</b></p> <p>International preliminary examination fee (37 CFR 1.482) not paid to USPTO          but international search fee (37 CFR 1.445(a)(2)) paid to USPTO. .... <b>\$740.00</b></p> <p>International preliminary examination fee (37 CFR 1.482) paid to USPTO          but all claims did not satisfy provisions of PCT Article 33(1)-(4) ..... <b>\$710.00</b></p> <p>International preliminary examination fee (37 CFR 1.482) paid to USPTO          and all claims satisfied provisions of PCT Article 33(1)-(4). .... <b>\$100.00</b></p> <p><b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b></p> <p>Surcharge of <b>\$130.00</b> for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30          months from the earliest claimed priority date (37 CFR 1.492(e)).</p> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th style="width:15%;">CLAIMS</th> <th style="width:20%;">NUMBER FILED</th> <th style="width:20%;">NUMBER EXTRA</th> <th style="width:20%;">RATE</th> <th style="width:25%;"></th> </tr> <tr> <td>Total Claims</td> <td>9 - 20 =</td> <td>0</td> <td>X \$18.00</td> <td>\$ 0</td> </tr> <tr> <td>Independent Claims</td> <td>4 - 3 =</td> <td>1</td> <td>X \$84.00</td> <td>\$ 84.00</td> </tr> </table> <p>MULTIPLE DEPENDENT CLAIM(S) (if applicable) Yes + \$280.00 \$ 280.00</p> <p style="text-align: right;"><b>TOTAL OF ABOVE CALCULATIONS = \$ 1384.00</b></p> <p><input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are          reduced by 1/2.</p> <p style="text-align: right;"><b>SUBTOTAL = \$ 1384.00</b></p> <p>Processing fee of <b>\$130.00</b> for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30          months from the earliest claimed priority date (37 CFR 1.492(f)). + \$</p> <p style="text-align: right;"><b>TOTAL NATIONAL FEE = \$ 1384.00</b></p> <p>Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be          accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). <b>\$40.00</b> per property + \$</p> <p style="text-align: right;"><b>TOTAL FEES ENCLOSED = \$ 1384.00</b></p> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:60%;"></td> <td style="width:20%; text-align: right;">Amount to be:</td> <td style="width:20%; text-align: center;">\$</td> </tr> <tr> <td></td> <td style="text-align: right;">refunded</td> <td></td> </tr> <tr> <td></td> <td style="text-align: right;">charged</td> <td style="text-align: center;">\$</td> </tr> </table>	CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		Total Claims	9 - 20 =	0	X \$18.00	\$ 0	Independent Claims	4 - 3 =	1	X \$84.00	\$ 84.00		Amount to be:	\$		refunded			charged	\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE																						
Total Claims	9 - 20 =	0	X \$18.00	\$ 0																					
Independent Claims	4 - 3 =	1	X \$84.00	\$ 84.00																					
	Amount to be:	\$																							
	refunded																								
	charged	\$																							

a. ☒ A check in the amount of \$ **1384.00** to cover the above fees is enclosed.

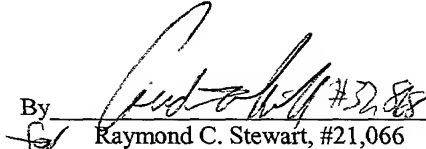
b. ☐ Please charge my Deposit Account. No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ to cover the above fees.  
 A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any  
 overpayment to Deposit Account No. 02-2448.

**NOTE:** Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR  
 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

Send all correspondence to:  
**Birch, Stewart, Kolasch & Birch, LLP** or Customer No. 2292  
 P.O. Box 747  
 Falls Church, VA 22040-0747  
 (703) 205-8000

**Date:** December 13, 2001

By  #32,888  
 Raymond C. Stewart, #21,066

JC13 Rec'd PCT/PTC 13 DEC 2001

PATENT  
0471-0268P

## IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant: BEVILACQUA, Carla et al.  
Int'l. Appl. No.: PCT/EP00/05383  
Appl. No.: NEW Group:  
Filed: December 13, 2001 Examiner:  
For: PHARMACEUTICAL COMPOSITIONS  
CONTAINING 8-CHLORO-3 (β-  
DIETHYLAMINOETHYL) -4-METHYL-7-  
ETHOXYCARBONYL-METHOXY COUMARIN  
BASE AND THE SALTS THEREOF, WITH  
CHOLESTEROL-LOWERING ACTIVITY

PRELIMINARY AMENDMENT**BOX PATENT APPLICATION**Assistant Commissioner for Patents  
Washington, DC 20231

December 13, 2001

Sir:

The following Preliminary Amendments and Remarks are respectfully submitted in connection with the above-identified application.

AMENDMENTSIN THE SPECIFICATION:

Please amend the specification as follows:

Before line 1, insert --This application is the national phase under 35 U.S.C. § 371 of PCT International Application No. PCT/EP00/05383 which has an International filing date of June 13, 2000, which designated the United States of America and was published in English.--

REMARKS

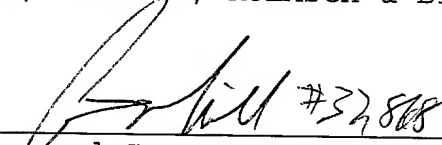
The specification has been amended to provide a cross-reference to the previously filed International Application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By

 #32,818  
Raymond C. Stewart, #21,066

RCS/sll  
0471-0268P

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3/pts

PHARMACEUTICAL COMPOSITIONS CONTAINING 8-CHLORO-3( $\beta$ -  
DIETHYLAMINOETHYL)-4-METHYL-7-ETHOXYCARBONYL-  
METHOXY COUMARIN BASE AND THE SALTS THEREOF, WITH  
CHOLESTEROL-LOWERING ACTIVITY

SUBJECT OF THE INVENTION

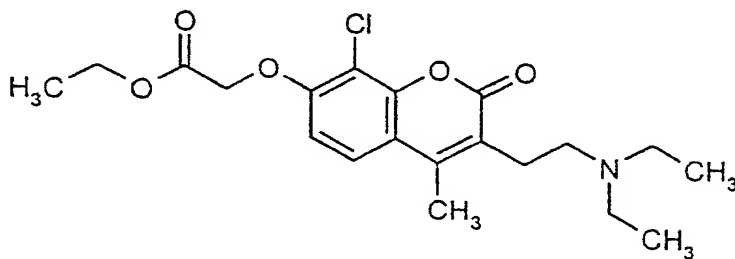
The present invention concerns the use of cloricromene (8-chloro-3( $\beta$ -diethylaminoethyl)-4-methyl-7-ethoxycarbonylmethoxy coumarin) base and the salts thereof to prepare pharmaceutical compositions with cholesterol-lowering activity.

FIELD OF THE INVENTION

Coumarins include a vast class of phenol substances found in plants, and they are constituted by a benzene ring and an  $\alpha$ -pyrone ring fused together.

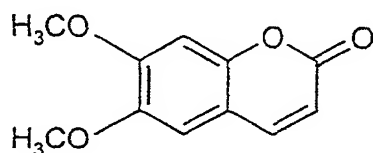
At least 1,300 coumarins have been identified to date, mainly as metabolites of green plants, in fungi and bacteria.

Cloricromene belongs to the coumarin family and is prepared by the process described in U.S. patents No.s 4,296,039 and 4,452,811 by the Applicant. Its formula is



The selective insertion of a chlorine atom in position 8 of the coumarin gives the molecule a coronary vasodilatory property, an antiarrhythmic activity (US 4,349,566) and an anti-platelet-aggregation activity (US 4,302,741); see also "The Merck Index", twelfth Edition, 2467.

It has now surprisingly been found that cloricromene can also be used as a cholesterol-lowering agent. Data in the literature indicate a cholesterol-lowering effect of a coumarin derivative of vegetable origin demonstrated on a single experimental model (Huang et al.: British Journal of Pharmacology 1993: 110: 1508-1514; Chen et al.: Morphological evidence for the antiatherogenic effect of scoparone of formula



in hyperlipidaemic diabetic rabbits. Cardiovascular Research 1994: 28: 1679-1685).

It is known that high plasma values of total cholesterol or cholesterol bound to the low density lipoprotein represent a major risk factor in arteriosclerotic phenomena responsible for most cases of myocardial or cerebral infarct.

In particular, when plasma cholesterol levels rise above 220 mg/dl, a marked increase in myocardial infarct has been observed.

High cholesterol levels are often seen in patients suffering from vascular diseases caused, for example, by old age, obesity or cardiac disorders.

The first step in treatment for all kinds of hyperlipoproteinaemia is to prescribe a diet to maintain normal body weight and to decrease the lipid concentration in the plasma.

Moreover, dyslipidaemic individuals should keep all other risk factors that might accelerate the arteriosclerotic process to a minimum, by treating hypertension, keeping in check their blood glucose levels in the case of diabetics, giving up smoking and taking plenty of physical exercise.

Lastly, the therapeutic strategy for hyperlipoproteinaemia consists in administering drugs able to reduce the plasma concentration of lipoproteins,

reducing their production or increasing their elimination from the plasma.

Of the drugs that reduce the concentration of lipoproteins in the plasma, we name nicotinic acid, clofibrate, gemfibrozil, probucol and resins that scavenge bile acids such as cholestyramine and colestipol, and simvastatin.

Unfortunately, said drugs cause various side effects such as intense hot flushes, itching, peptic ulcers, hyperpigmentation of the skin, nausea, vomiting, hair loss, weakness, impotence and gastrointestinal disorders. Unlike these drugs, cloricromene can be administered over long periods of time without causing any side effects. Lastly, there are no tolerability data to support the use of scoparone in cholesterol-lowering therapies in humans, because the molecule has not been assessed in clinical trials of any kind.

#### DETAILED DESCRIPTION OF THE INVENTION

It has been found, surprisingly, that cloricromene is able to reduce cholesterol levels in the blood, and it can therefore be used to advantage in the preparation of pharmaceutical compositions with cholesterol-lowering activity.

This activity has proved to be particularly marked in patients suffering from vascular disorders and/or cholesterol levels of over 190 mg/dl.

#### TEST TO COMPARE THE TOLERABILITY AND CHOLESTEROL- LOWERING EFFECT OF CLORICROMENE AND SCOPARONE IN

#### EXPERIMENTAL MODELS IN RABBIT

##### Test No. 1

A preliminary experiment was performed to assess the ability of cloricromene to reduce plasma levels of cholesterol and triglycerides in rabbits fed on a high-fat diet, treated chronically for 4-5 weeks. As reference product we used scoparone, as it is the only coumarin derivative of vegetable origin with a documented effect on these parameters.

The experimental model induces high levels of cholesterol and triglycerides in the plasma by a 1% cholesterol-enriched diet, simultaneously inducing diabetes

by injection of alloxan, a highly toxic product for the  $\beta$  cells of the pancreas. In this way, it is possible to reach very high values of cholesterol and triglycerides in the system rapidly. The body weight of the animals and the plasma levels of the test parameters were assessed weekly throughout the experiment. The results of this preliminary experiment indicate that the group of rabbits treated with cloricromene present a body weight increase curve which is superimposable on that of the control group of animals, which had diabetes and hypercholesterolaemia but were not receiving any pharmacological treatment. Conversely, in the group of animals treated with scoparone, a marked and progressive reduction in body weight was observed in the animals, which indicated beyond doubt poor tolerability of the pharmacological treatment. The plasma levels of cholesterol and triglycerides too tended to be lower in the group treated with cloricromene than in the group treated with scoparone.

The results are reported in Figure 1.

These data highlight, in comparison to scoparone, cloricromene's absolute lack of toxic activity even when administered repeatedly over long periods of time.

#### Test No. 2

In the same experimental model, in which a diabetic pathology is induced by treating the animals with alloxan, and hypercholesterolaemia is induced by administering a 1% cholesterol diet, we monitored at weekly intervals the cholesterol levels of the rabbits, which had been divided into the following treatment groups:

1. Control, treated with saline solution
2. Scoparone
3. Cloricromene

The results reported in Figure 2 show that cholesterol levels in the group of animals treated with cloricromene are markedly lower than those of both the control group and that treated with scoparone. The difference is evident as early as



the third week of treatment. In this experiment, as in the previous one, the product proved to be practically free from any toxic effects: indeed, at the end of the experiment, the number of animals that completed the treatment with scoparone was considerably lower than the number of those treated with cloricromene.

### 5 Test No. 3

As further confirmation of this interesting result, we prepared another experimental model. In this case, hypercholesterolaemia was induced in rabbit by administration of a 0.1% cholesterol diet, without simultaneously inducing diabetes. In these experimental conditions, cholesterol levels of around 250 mg/dl were obtained, that is to say, values that are compatible with the pathological situation normally observed in humans affected by hypercholesterol. The rabbits were divided into three treatment groups: controls treated with saline, a second group receiving scoparone and a third receiving cloricromene. The results in this case too showed that cholesterol levels were markedly lower in the group treated with cloricromene than in the control group that received no treatment and in the group of animals which received scoparone (Figure 3).

## CHOLESTEROL-LOWERING AND ANTITHROMBOTIC EFFECTS OF CLORICROMENE

We conducted a multicentre, double-blind, randomised study, controlled versus placebo, on 159 patients with Peripheral Vascular Disease (PVD) at Fontaine stage II, the classic symptom of which is Intermittent Claudication (IC).

PVD is a pathology involving thrombotic risk, and IC patients run a two- to fivefold greater risk of cardiovascular ischemic diseases than other subjects, with a particularly high mortality rate from myocardial infarct, stroke and thrombosis.

Hypercholesterolaemia is beyond doubt one of the risk factors in the genesis of the atherosclerotic processes that lead to the formation of atheromatous plaques.

It has also been demonstrated that vessel walls altered by atheromatous

plaques may give rise to interactions of the endothelium with the circulating cells (mainly platelets and leukocytes) that trigger the thrombotic process.

In our study, besides assessing the effect of cloricromene on IC, we also studied the cholesterol-lowering effects of the drug and the incidence of major cardiovascular events (myocardial infarction, stroke, vascular death, progression to Fontaine stages III-IV) after a treatment period of six months.

In analysing the cholesterol-lowering effect, 117 patients were considered who presented cholesterol values at baseline of over 190 mg/dl.

The critical value of 190 mg/dl was selected on the basis of data from the international literature that report this value as the risk threshold in pathologies such as cardiac ischaemia and atherosclerosis in general, in which excessive cholesterol represents a real risk factor. Therefore, the patients who presented cholesterol values equal to or over 190 mg/dl were considered to be at risk from said pathologies.

For the purposes of this analysis, 58 patients were treated for 6 months with 200 mg of cloricromene per day (one capsule of 100 mg twice a day), while the remaining 59 patients were treated with placebo (Table). All the patients also took aspirin at a dose of 160 mg/day throughout the trial.

**Table**

Group	Cholesterol levels at Week 0	Cholesterol levels at week 24	p
Group treated with Cloricromene	243±31	229±32	p=0.0035
Placebo group	234±30	234±39	p=ns

ns = not significant

From analysis of the covariance, the estimation of the difference between the treatment groups proves statistically significant in favour of the group treated with cloricromene (p=0.04, with a value of  $\alpha=0.05$ ).

As regards the onset of severe events, no major cardiovascular events or deaths were observed in either group.

The results suggest that cloricromene may be useful in controlling thrombotic risk, by lowering cholesterol levels and inhibiting cellular interactions (endothelial cells, platelets, leukocytes) which might otherwise contribute towards the formation of thrombi, with the subsequent risk of major cardiovascular events.

#### FORMULATION EXAMPLES

##### Capsules

Cloricromene	100	mg
Saccharose	92.77	mg
Maize starch	30.93	mg
Magnesium stearate	34.6	mg
Povidone	25.48	mg
Monobasic potassium phosphate	20.8	mg
Cellulose acetate	95.42	mg
Gelatin container	77	mg

##### Injectable composition

Cloricromene hydrochloride	30	mg
Mannitol	30	mg
Sodium chloride	45	mg
Water for injection	5	ml

The formulations being thus described in detail, it is obvious that they can be modified in various ways. Such modifications are not to be considered as variations from the spirit and purpose of the invention, and any such modification which may appear obvious to an expert in the specific sector are to be considered as coming within the scope of the following claims.

CLAIMS

1. Pharmaceutical compositions containing cloricromene base or a salt or derivative thereof for reducing cholesterol levels in patients suffering from hypercholesterolaemia.

2. Use of cloricromene base and / or its relative salts and derivatives for the preparation of pharmaceutical compositions with cholesterol-lowering activity.

3. Use of cloricromene base and / or its salts and derivatives for the preparation of pharmaceutical compositions with cholesterol-lowering and antithrombotic activity.

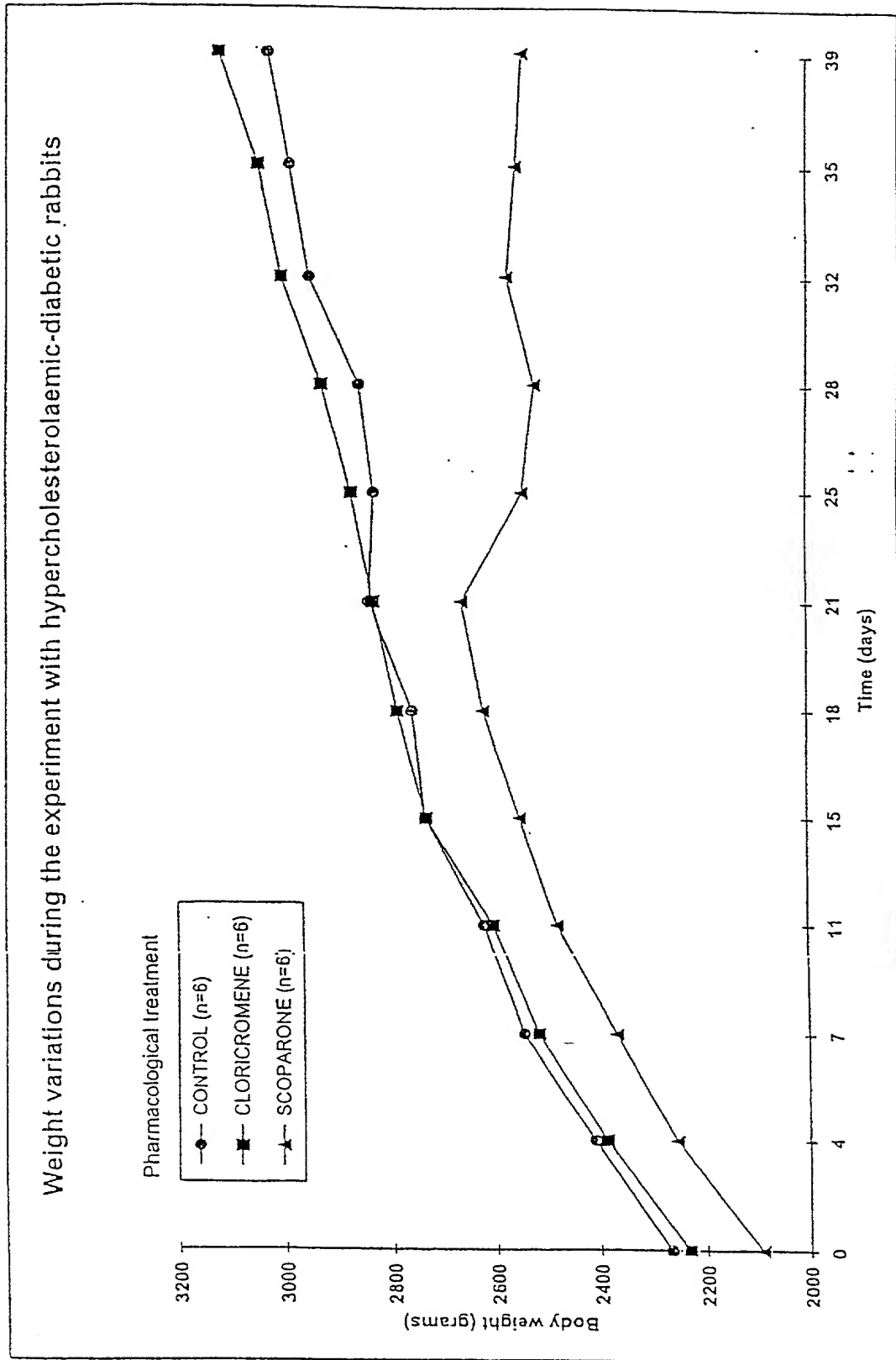
4. Use of cloricromene base and relative salts and derivatives for the preparation of pharmaceutical compositions with cholesterol-lowering activity in patients with cholesterol levels in the plasma of over 190 mg/dl.

5. Use according to claims 1 - 4, wherein the pharmaceutical compositions are in the form of capsules, tablets, injectable solutions, controlled release systems, transdermal systems.

6. Use according to the present claims, wherein the cloricromene salt is sodium hydrochloride.

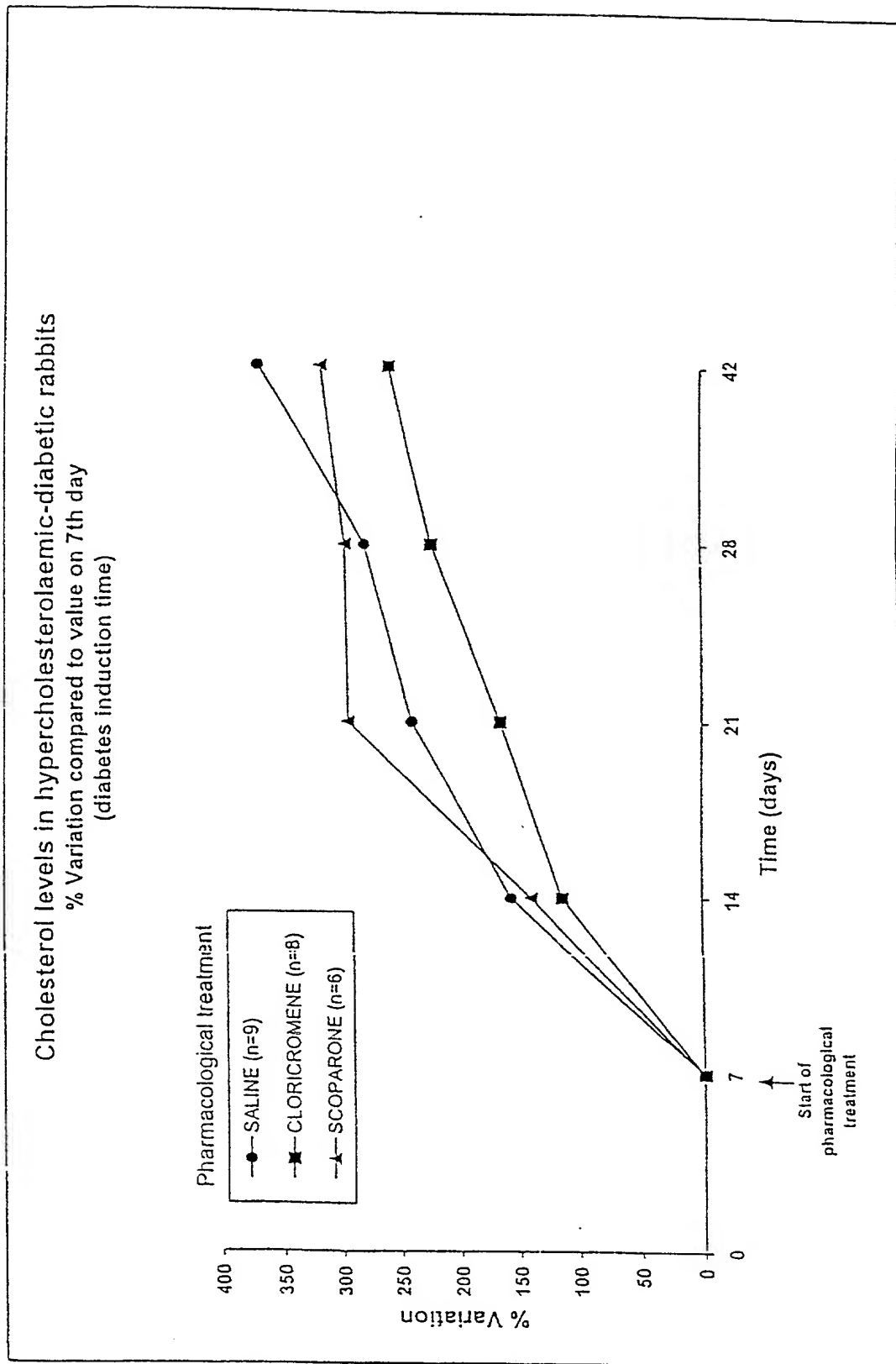
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FIGURE 1



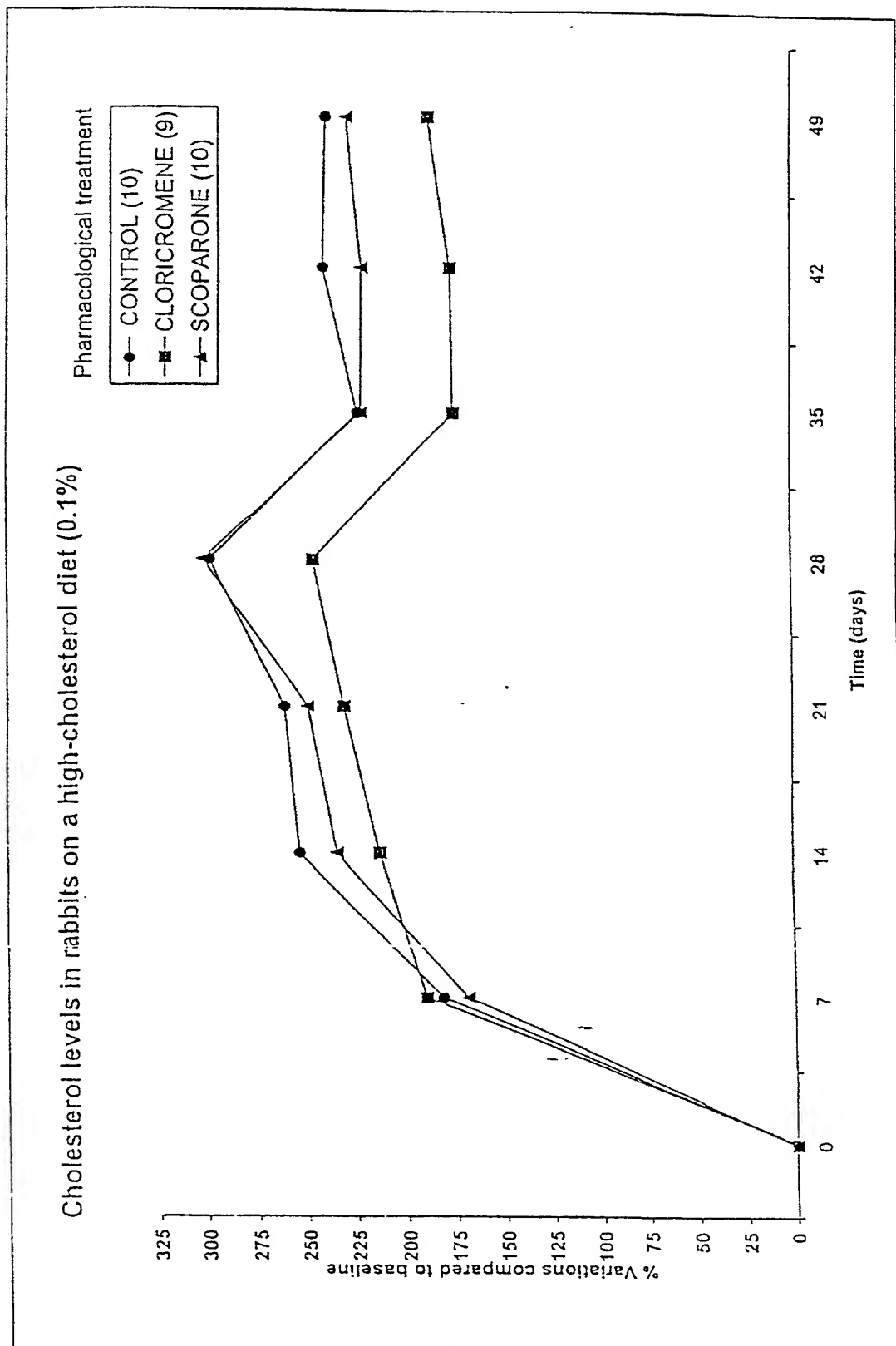
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FIGURE 2



3/3

FIGURE 3



9634v

# BIRCH, STEWART, KOLASCH & BIRCH, LLP

P.O. Box 747, Falls Church, Virginia 22040-0747

Telephone: (703) 205-8000 • Facsimile: (703) 205-8050

Attorney Docket No.:

0471-0268P

PLEASE NOTE:  
YOU MUST  
COMPLETE THE  
FOLLOWING

## COMBINED DECLARATION AND POWER OF ATTORNEY FOR PATENT AND DESIGN APPLICATIONS

As a below named inventor, I hereby declare that: my residence, post office address and citizenship are as stated next to my name; that I verily believe that I am the original, first and sole inventor (if only one inventor is named below) or an original, first and joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Insert Title: Pharmaceutical compositions containing 8-chloro-3(β-diethylaminoethyl

Fill in Appropriate Information -  
For Use Without Specification Attached:  
the specification of which is attached hereto. If not attached hereto,  
the specification was filed on \_\_\_\_\_ as  
United States Application Number \_\_\_\_\_  
and amended on \_\_\_\_\_ (if applicable) and/or  
the specification was filed on 13.06.2000 as PCT  
International Application Number PCT/EP00/05383  
amended under PCT Article 19 on \_\_\_\_\_ (if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I do not know and do not believe the same was ever known or used in the United States of America before my or our invention thereof, or patented or described in any printed publication in any country before my or our invention thereof or more than one year prior to this application, that the same was not in public use or on sale in the United States of America more than one year prior to this application, that the invention has not been patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by me or my legal representative or assigns more than twelve months (six months for designs) prior to this application, and that no application for patent or inventor's certificate on this invention has been filed in any country foreign to the United States of America prior to this application by me or my legal representatives or assigns, except as follows.

I hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Insert Priority Information:  
(if appropriate)

### Prior Foreign Application(s)

### Priority Claimed

<u>PD99A000128</u> (Number)	<u>Italy</u> (Country)	<u>14.06.1999</u> (Month/Day/Year Filed)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
_____ (Number)	_____ (Country)	_____ (Month/Day/Year Filed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
_____ (Number)	_____ (Country)	_____ (Month/Day/Year Filed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
_____ (Number)	_____ (Country)	_____ (Month/Day/Year Filed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional applications(s) listed below.

Insert Provisional Application(s):  
(if any)

_____ (Application Number)	_____ (Filing Date)
_____ (Application Number)	_____ (Filing Date)

All Foreign Applications, if any, for any Patent or Inventor's Certificate Filed More than 12 Months (6 Months for Designs) Prior to the Filing Date of This Application:

Country	Application Number	Date of Filing (Month/Day/Year)
---------	--------------------	---------------------------------

Insert Requested Information:  
(if appropriate)

_____	_____	_____
_____	_____	_____

I hereby claim the benefit under Title 35, United States Code, §120 of any United States and/or PCT application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States and/or PCT application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose information which is material to the patentability as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

Insert Prior U.S. Application(s):  
(if any)

_____ (Application Number)	_____ (Filing Date)	_____ (Status - patented, pending, abandoned)
_____ (Application Number)	_____ (Filing Date)	_____ (Status - patented, pending, abandoned)



I hereby appoint the following attorneys to prosecute this application and/or an international application based on this application and to transact all business in the Patent and Trademark Office connected therewith and in connection with the resulting patent based on instructions received from the entity who first sent the application papers to the attorneys identified below, unless the inventor(s) or assignee provides said attorneys with a written notice to the contrary:

Raymond C. Stewart	(Reg. No. 21,066)	Terrell C. Birch	(Reg. No. 19,382)
Joseph A. Kolasch	(Reg. No. 22,463)	James M. Slattery	(Reg. No. 28,380)
Bernard L. Sweeney	(Reg. No. 24,448)	Michael K. Mutter	(Reg. No. 29,680)
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Leonard R. Svensson	(Reg. No. 30,330)	Terry L. Clark	(Reg. No. 32,644)
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Full Name of Fifth  
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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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GIVEN NAME/FAMILY NAME		INVENTOR'S SIGNATURE	DATE*
Residence (City, State & Country)		CITIZENSHIP	
POST OFFICE ADDRESS (Complete Street Address including City, State & Country)			

\*DATE OF SIGNATURE